

USER MANUAL

EASY GO *VAC* ASPIRATOR



PM66 Series
PM66Li (Shown)

SAVE THESE INSTRUCTIONS

*For the most current manual revision,
please visit our Website: www.precisionmedical.com*

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ISO 13485 Certified

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. *Easy Go Vac Aspirator* from packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Provider.

INTENDED USE

The Easy Go Vac Aspirator provides a portable, AC/DC powered medical vacuum source. It is intended for use in the homecare / healthcare environments.

❗ Only use this Aspirator for its Intended Use.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a Professional to install and operate the Easy Go Vac Aspirator. The Easy Go Vac Aspirator is to be used only by trained professional caregivers in a home or hospital environment.

The Easy Go Vac Aspirator is to be used only by adults capable of reading and understanding the Instructions of Use written in the appropriate language.

This manual is provided for your training, safety and to prevent damage to the Aspirator. If you do not understand this manual, DO NOT USE the Aspirator and contact your Provider.

EXPLANATION OF ABBREVIATIONS

mmHg Millimeters of Mercury l/min Liters per Minute
inHg Inches of Mercury

SAFETY INFORMATION - WARNINGS AND CAUTIONS

 **DANGER**

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

 **WARNING**

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

 **CAUTION**

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

CAUTION

Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.



PM66 SERIES WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2012, 3.1 ed), CAN/CSAC22.2 No. 60601-1 (2014) 62NA



Caution! U.S. Federal Law restricts this device to sale by or on the order of a physician.



This device may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash. Contact your local waste Management for disposal of Electronic Equipment.



Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards.



Operating Instructions



Follow Instructions for Use



General Warning Sign



General Mandatory Action Sign



Date of manufacture



Manufacture



Serial Number



Model Number



Type BF applied part



Class II Equipment



Push to Activate



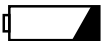
DO NOT disassemble



Battery



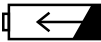
Degree of protection against ingress of solids and/or liquids



Battery Low



Alternating Current



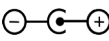
Battery Charging



Direct Current



Battery Full



DC power connection, Positive Center.



"ON" for part of equipment



"OFF" for part of equipment



Single Use

The PM66 Series Aspirators meet the requirements of IEC 60601-1-2 and are considered safe from producing electromagnetic interference with other devices when used normally in accordance with their intended use. Should the aspirator cause any interference, try repositioning it or moving it to another location.

DANGER

To reduce the risk of Electrocution:

- Always unplug the Aspirator after using, except when battery is being recharged.
- **DO NOT** use, place or store the Aspirator where it can fall or be pulled into a tub, sink, water or other liquids. Unplug from wall immediately.
- **DO NOT** attempt to repair the Aspirator. Any attempt could result in electrical shock.
- Caution must be exercised when operating the Aspirator where oxygen is being administered.
- The Aspirator is not suitable for use in an enriched environment of flammable anesthetic mixture with air, oxygen or nitrous oxide.

WARNING

To reduce risk of burns, electrocution, fire, or injury to persons:

- Close supervision is necessary when this Aspirator is used by, on, or near children or patients with special needs.
- Use this Aspirator only for its "Intended Use" as described in this manual.
- Use of accessories and connecting parts not designed for this Aspirator may affect performance and/or cause damage to the device.
- **DO NOT** use if the Aspirator has been damaged.
- **DO NOT** clean the Aspirator with harsh or flammable chemicals.
- If the Aspirator tubing becomes occluded against patient's tissue, powering off the device may not release tubing.
- No modifications to this device are allowed.
- The negative pressure of the unit must be checked by occluding the end of the suction tubing before attaching it to the suction catheter, and prior to each suctioning event. Suction pressure should be set as low as possible to be effective.
- The connection of high vacuum / high flow devices to low flow accessories has the potential to harm the patient.

CAUTION

- **DO NOT** store or operate the Aspirator outside the specified environmental conditions.
- Patients with special needs may require assistance to operate the Aspirator.
- Incorrect accessories connected to this device may affect the device flow performance.
- **DO NOT** allow Aspirator to exceed Operating or Storage Temperature specifications.

SPECIFICATIONS

For technical specifications contact Precision Medical, Inc.
or visit www.precisionmedical.com

Suction Canister: 800ml/1200ml Max Volume - Lid has a float shut off valve that protects the Aspirator from overfill.

Vacuum is not to exceed 25 inHg (635 mmHg)

Patient Tubing: 1/4 in. ID Non-Conductive PVC tubing, 6 ft. long, with 1/4 in.- 3/8 in. ID female connectors

Inlet Filter: Inline, Bacterial Filter (included)

Inline, Hydrophobic Filter (optional)

Operating Vacuum Range: ~2 to ≥ 19 inHg (~51 to ≥ 483 mmHg)

Electrical:

Car Charger (DC): 12 Volts, 1.8 Amps

Household Current (AC): 100 - 240 Volts, 50-60 Hz, 0.35 - 0.80 - Amps, 60 Watts

Internal Battery Type:

Battery (PM66S): 12 Volt, Sealed Lead Acid

Battery (PM66Li): 14.8 Volt, 4 cell Lithium Ion

Operating Temperature Range: 0°F to 122°F (-18°C to 50°C)

Storage / Transport Requirements:

Temperature Range: -40°F to 160°F (-40°C to 71°C)

Maximum Humidity: 95% Noncondensing

Duty Cycle: 15 Min ON / 15 Min OFF / within a 2 Hour cycle

Run Time: approx 1 hour (using internal battery)

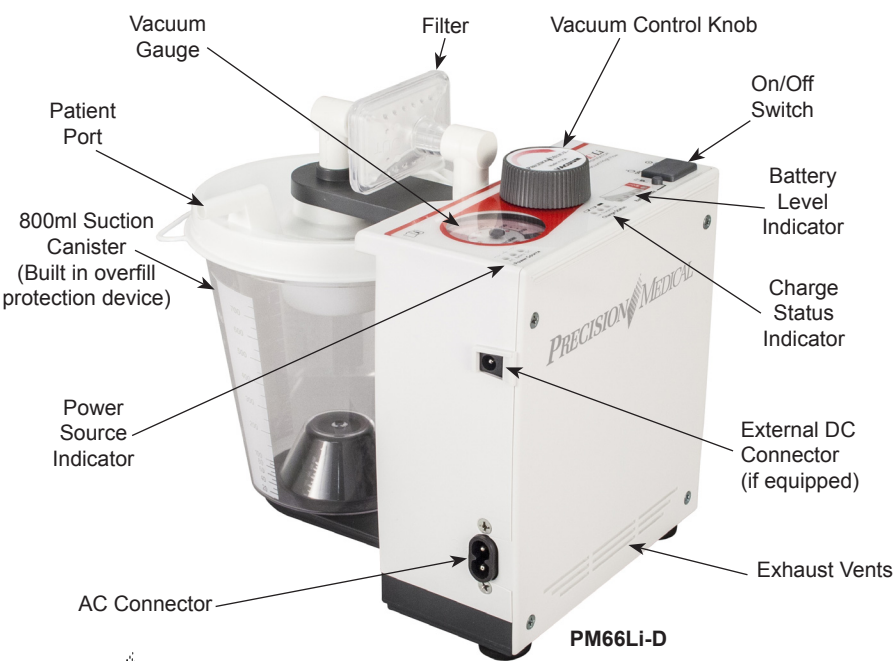
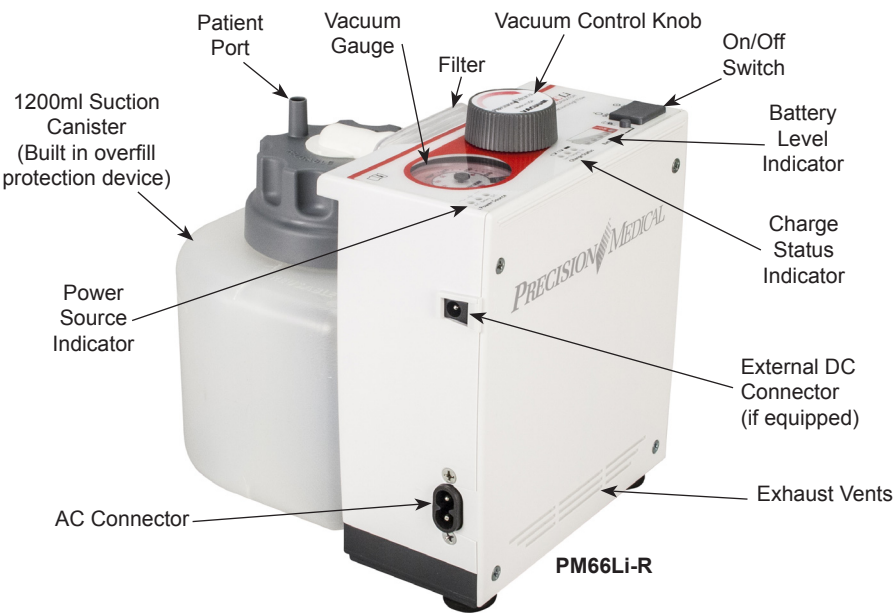
Charge Time: 2-3 hours

Specifications are subject to change without prior notice.

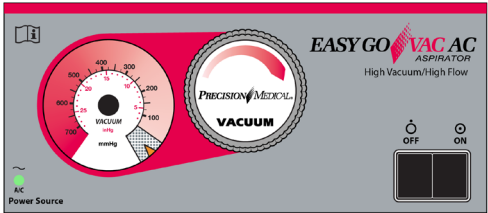
COMPONENT IDENTIFICATION

 CAUTION

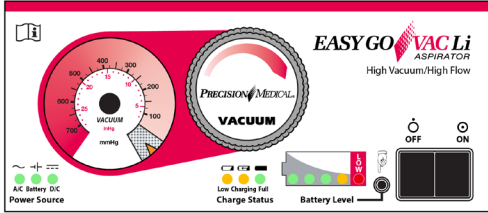
If for any reason any label becomes illegible or lost, contact Precision Medical, Inc.



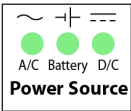
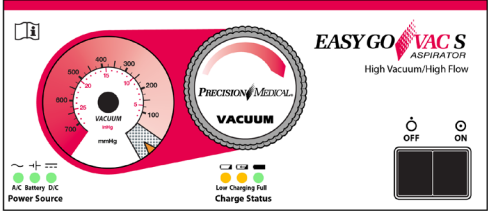
PM66AC (AC ONLY)



PM66Li (Lithium Ion)

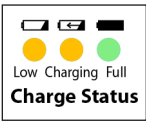


PM66S (Sealed Lead Acid)



Power Source

When light is GREEN the indicated power source is being used.

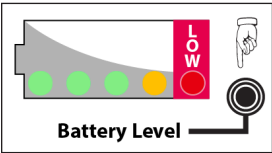


Charge Status (if equipped)

LOW - The power switch is ON, AC not plugged in and light is AMBER, the Aspirator Internal Battery requires charging.

CHARGING - The power switch is OFF, AC is plugged in and light is AMBER, the Aspirator is in the charging process.

FULL - The power switch is OFF, AC is plugged in and light is GREEN, the Aspirator Battery is fully charged.



Battery Level (Li model only)

Push to check battery level

GREEN - Level is Good

AMBER - Level is getting Low

RED - Recharge required

⚠ CAUTION

DO NOT run the Aspirator without the Inline Filter, using aspirator without filter will void the warranty.

Do not remove or damage canister overfill protection device.

If liquid and/or solid material has been drawn into the device, immediately stop using the device and contact your equipment provider.

Bacteria Filter will not stop liquid from entering the device.

OPERATING INSTRUCTIONS

1. Charge Device *

Plug into wall outlet

Power "OFF"

Full charge
2 to 3 hrs.

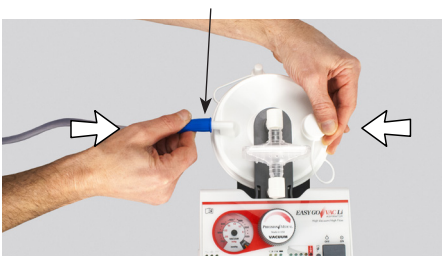
*PM66Li and PM66S models only

2. Connect to power source (for external power operation)



3. Connect suction tubing to canister

Push together



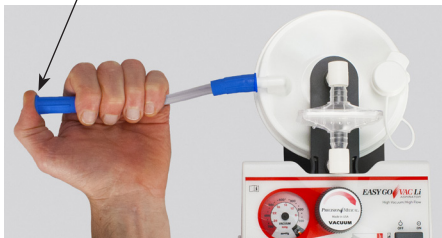
4. Power "ON"

Push button



5. Block suction tubing

Block end to set
vacuum level



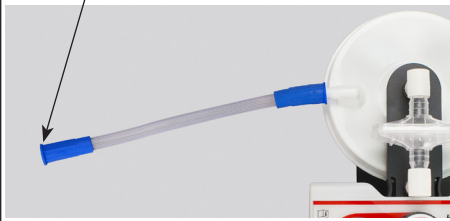
6. Adjust knob to desired vacuum level on gauge



OPERATING INSTRUCTIONS (continued)

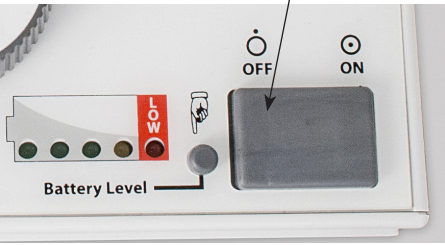
7. Perform Procedure

Connect patient suction attachment/perform procedure



8. Power “OFF” when procedure completed

Push button



⚠ CAUTION

- Verify battery charge (if equipped) prior to use.
- Charging Light is on when Aspirator is plugged in and is in the “OFF” (O) position only.
- If automatic shut off occurs during battery operation, the Aspirator cannot be restarted until the battery has been recharged or until the Aspirator is connected to either of the external power source options (AC or DC).

⚠ WARNING

Operating Aspirator after Amber **Low Battery Light** has been on continuously, will cause automatic shut down.

Device in carry bag



CLEANING / MAINTENANCE

 WARNING

- Turn the Aspirator “OFF” (Ö) and disconnect from any external power source before cleaning.
- **DO NOT** clean the Aspirator with Alcohol, Acetone or other solvents.

CAUTION

- Tubing is single patient use only. DO NOT clean.
 - Canister is single patient use only.
- 

MAINTENANCE

Vacuum/Flow verification should be checked by the device provider as necessary - Recommended annually or between patients.

Cleaning for Exterior Components:

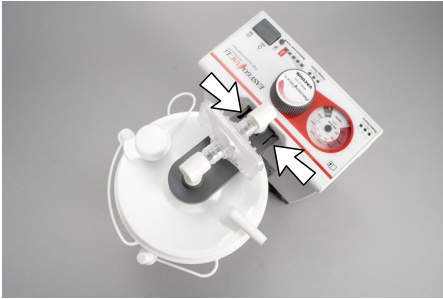
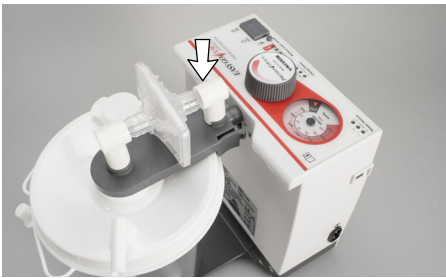
1. Disconnect the Aspirator from power source and other connections before cleaning.
2. Use a cloth or sponge dampened with mild soap and water.
3. Wipe dry with a clean cloth or paper towel.
4. Store the Aspirator in a clean area free from grease, oil, and other sources of contamination.

1200cc canister (reusable) can be cleaned with a mild detergent or placed on top rack of dishwasher.

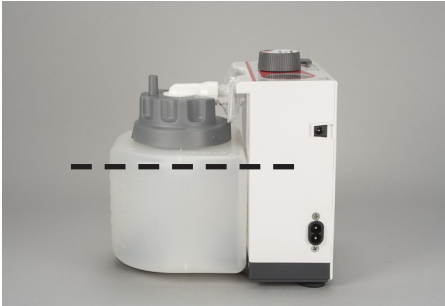
For institutional cleaning:

- Exterior: Hospital approved quaternary cleaner; i.e., Sporociden®
- Reusable canister: Cydex® or equivalent

CANISTER REMOVAL/ASSEMBLY (800cc Disposable)

1. Push tabs to release canister	2. Pull canister away from device
	
3. Remove lid, empty & clean	4. Reinstall lid securely
	
5. Place canister on base	6. Align canister assembly with inlet port and locking tabs with openings on device
	
7. Push together until they engage (click)	8. Correctly reassembled
	

CANISTER REMOVAL/ASSEMBLY (1200cc Reusable)

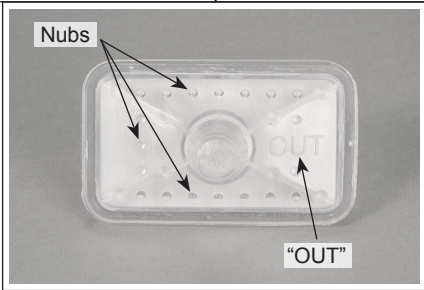
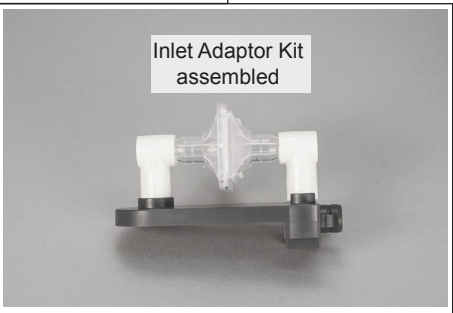
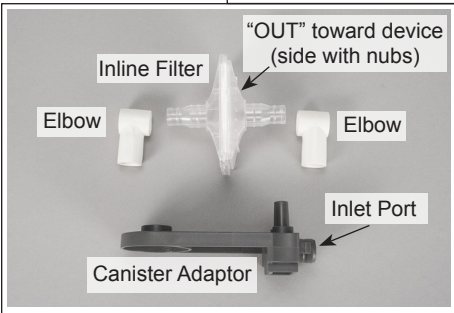
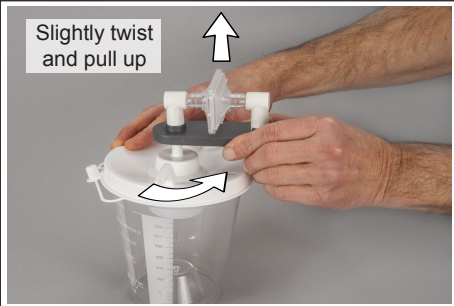
1. Grasp filter and pull apart 	2. Tilt off base to remove 
3. Remove lid, empty & clean 	4. Place lid on canister 
5. Align indicators on lid and canister 	6. Tilt and place canister on device base 
7. Align with port & push together 	8. Correctly installed canister is level 

INLINE FILTER REPLACEMENT

CAUTION

- When installing inline filter be sure the side that has small nubs and says “OUT” is facing toward inlet port on device.
- Filter cannot be cleaned. If it becomes contaminated or clogged, it must be replaced.

800cc Disposable Canister Inlet Adaptor Kit



1200cc Reusable Canister



“OUT” toward device
(side with nubs)

RETURNS

Returned products require a Returned Goods Authorization (RGA) number, contact Precision Medical, Inc. All returns must be properly packaged to prevent shipping damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com. Precision Medical will NOT repair contaminated devices (biohazard).

DISPOSAL INSTRUCTIONS

Dispose of Biohazard waste as described by your Healthcare Professional or Healthcare Facility protocol.



WARNING

- The Aspirator may contain an internal battery. Batteries contain materials which can contaminate the environment when improperly disposed of. Dispose of the Aspirator in accordance with local regulations.
- If Aspirator is used for treatment of infectious disease, consult your Physician or Healthcare Professional for recommended procedures for proper disposal.
- This device may contain electrical components that are hazardous to the environment. DO NOT dispose device into standard trash. Contact your local waste Management for disposal of Electronic Equipment.



TROUBLESHOOTING

If the Aspirator fails to function, consult this Troubleshooting section. If the problem cannot be corrected, consult your Provider.
There are no user serviceable parts inside this device. DO NOT open case.

Problem	Probable Cause	Remedy
Aspirator will not operate on battery	1. On/Off Switch in “OFF” position 2. Battery not charged (Low battery light on)	1. On/Off Switch to “ON” position 2. •Recharge battery •If battery will not charge, contact your Provider
Aspirator will not operate when connected to AC Power Source	1. On/Off Switch in “OFF” position 2. AC Power Cord not connected	1. On/Off Switch to “ON” position 2. Check connection at both AC Power Source and Aspirator

Continued on next page.

TROUBLESHOOTING continued

Problem	Probable Cause	Remedy
Aspirator will not operate when connected to Auto DC Power Cord	1. On/Off Switch in "OFF" position 2. Car not turned on. 3. Auto DC Power Cord not connected properly 4. Defective auto power port receptacle 5. Defective Auto DC Power Cord	1. On/Off Switch to "ON" position 2. Turn on car to activate it's DC outlet 3. Check connections at both ends of cord 4. Connect to a known working auto power port 5. Contact your Provider
Battery will not charge	1. Not connected to AC power source 2. Defective battery	1. Connect to AC power source 2. Contact your Provider
Unable to achieve desired vacuum setting	1. Filter not connected properly 2. Filter not installed correctly. 3. Suction Canister not connected properly 4. Defective Suction Canister 5. Defective Aspirator 6. Suction Tubing Leaks	1. Confirm and tighten connections 2. Confirm orientation of filter. 3. Confirm and tighten connections 4. Replace Suction Canister 5. Contact your Provider 6. Replace Suction Tubing
Inlet Filter becomes blocked by fluid (Hydrophobic only)	1. Collection Canister overflow mechanism failed	1. Replace Collection Canister 2. Replace Filter
Aspirator stops running, power switch "ON", battery or AC power applied	1. Device overheating	1. Power "OFF" device and allow cooling. 2. Ensure device has adequate ventilation. Ensure vents are not blocked.

ACCESSORY / REPLACEMENT PARTS

! *Only use accessories designed for use with this Aspirator.*

- Use tubing intended for suction only.
- Use Collection Canisters designed for use with this Aspirator only.
- Use Precision Medical: *Inlet Filter, External AC & DC Power Cord & Carry Bag Only*

Description	Part #
*Inlet Filter (Hydrophobic)	506851
Inlet Filter (Bacterial)	507754
800cc Canister, (Case-10 ea.)	502519-10
800cc Inlet Adapter Kit	507521
1200cc Canister	507522
Patient Suction Tubing	1955
Carry Bag	507263
AC Power Cord	506961
Auto DC Power Cord	507213

*Hydrophobic Filter will provide higher level of protection, stopping the egress of liquid into the device, if canister overfill protection should fail.

DECLARATION OF CONFORMITY



Precision Medical, Inc.
300 Held Drive
Northampton PA 18067, USA
Emergo Europe (European Office)
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2513 BH, The Hague
The Netherlands

Phone: +31 (0) 70.345.8570 Fax: +31 (0) 70.346.7299
PM66AC-R, PM66AC-D, PM66S-R, PM66S-D,
PM66LI-R & PM66LI-D



Classification:

Ila

Classification criteria:

Clause 3.2 Rule 11 of Annex IX of MDD

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II, 3 of the Directive 93/42/EEC and Directive 2007/47/EC on medical devices.

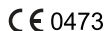
We certify that the production quality system conforms to the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed above.

Applied Standards: BS EN 1041, EN 60601-1, EN 60601-1-2, EN ISO 10079-1, EN ISO 14971, ISO 15223-1, ISO 13485

Notified Body:



AMTAC Certification Services Limited



Address: Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK

Certification Registration No's: 1126 A CE

Date of Expiry: 03 August 2017

Devices already manufactured: S/N traceability Device History Records

Validity of DOC: 04 August 2012 to Date of Expiry

Manufacture Representative: Quality Manager

Position: Quality Systems/ISO Representative

Date of Issue: 04 August 2012

LIMITED WARRANTY AND LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that Easy Go Vac Aspirator (the Product) and the following component parts thereof will be free of defects in workmanship and/or material for the following periods:

Easy Go Vac Aspirator Two (2) years from shipment

Battery Six (6) months from shipment

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, correct such defect by suitable repair or replacement at its own expense.

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES.

The representatives of Precision Medical, Inc. or any retailers are not authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. Thus, this writing is a final, complete and exclusive statement of the terms of that contract.

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHER WARRANTY OF QUALITY, WHETHER EXPRESS OR IMPLIED.

Precision Medical, Inc. shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

